MDPO Frame System
510(k) Summary
K093753

AUG 2 6 2010

Device Manufacturer: MDPO LLC
1560 Sawgrass Corporate Pkwy
Suite 400
Sunrise, FL 33323

Primary Contact: **Marcos Velez-Duran**
M Squared Associates, Inc.
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Proprietary Name: MDPO Frame System

Classification Name: 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Common Name: External Fixation Frame Components

Device Class: Class II

Product Codes: KTT and JDW

Device Description and Intended Use:

The MDPO Frame System is an external fixation system that can be made into various configurations for lower limb application. The MDPO Frame System includes the following components: Half Pins, Wires, Footplate consisting of the Connecting Plate/Assembly with interchanging Medial and Lateral Arch Plates/Assemblies, Matching Rings, Open Rings, Closed Circular Rings, Columns, Threaded Rods, Sockets, Screws, Bolts, Nuts, Washers, Posts, and Cubes.

The components of the MDPO Frame System are made from stainless steel, carbon fiber, Radel or aluminum.

All components are designed for single use only.

The MDPO Frame System is indicated for use in the lower extremity for: open and closed long bone fracture fixation, to include tensioned wire fixation of periarticular fractures, arthrodesis, osteotomy, reconstruction, non-unions, pseudoarthrosis, correction of bony or soft tissue defects and deformities, dislocations, arthrodiastasis, and Charcot foot reconstruction and Lisfranc dislocations.

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Predicate Devices:
The MDPO Frame System is similar to several predicates including the following:

- Smith & Nephew Ilizarov External Fixation System (K870961, K962808, K994143)
- DePuy ACE-Fischer External Fixation System (K083789)
- Biomet Vision FootRing System (K071395, K093057)

Technological Characteristics
The MDPO Frame System was characterized and evaluated according applicable requirements outlined in ASTM F1541-02 (2007), Standard Specification and Test Methods for External Fixation Devices and the FDA Reviewers Guidance Checklist for Orthopedic External Fixation Devices. Specifically, construct fatigue testing and in-plane compression strength testing were conducted. Construct fatigue testing was conducted on the MDPO Frame System and the Ilizarov External Fixation System and it was determined that the MDPO Frame System was at least equivalent in strength to the Ilizarov External Fixation System. In-plane compression strength testing of the simple bridge ring elements was also conducted on both the MDPO Frame System and the Ilizarov External Fixation System. The strength testing also confirmed that the MDPO Frame System is at least equivalent to the Ilizarov External Fixation System.

Substantial Equivalence Information:
The MDPO Frame System is similar to legally marketed devices including the Smith & Nephew Ilizarov External Fixation System, DePuy ACE-Fischer External Fixation System, and the Biomet Vision FootRing System. The MDPO Frame System has similar indications for use and technological characteristics as these predicate systems. While MDPO Frame System includes stainless steel Rods and Radel Columns and the predicate systems utilize stainless steel rods, construct fatigue testing confirmed that the Radel Columns are substantially equivalent to the Ilizarov stainless steel rods. Therefore, the MDPO Frame System is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MDPO, LLC
% M Squared Associates, Inc.
Mr. Marcos Velez-Duran
901 King Street, Suite 200
Alexandria, Virginia 22314

AUG 2 6 2010

Re: K093753
Trade/Device Name: MDPO Frame System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: July 12, 2010
Received: July 13, 2010

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Bruchinson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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Device Name: MDPO Frame System

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093753